REMARKS

Applicants respectfully request entry of the foregoing and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow.

Claims 26, 28-50, 53, 54 and 121 are pending in the application.

By the above amendments, Applicants amended Claims 53 and 121 to further define exemplary embodiments. For example, Applicants amended Claim 121 to further specify topical application to sensitive skin in at least one cutaneous region of the face, neck, hair and nails. Support for this amendment can be found at least at page 5, lines 14-17 of the specification. No new matter is added.

Applicants thank the Examiner for acknowledging entry of Applicants' Request for Continued Examination (RCE) dated April 6, 2006.

Turning now to the Official Action, Claims 26, 28, 32-34, 45-46, 116 and 121 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or under § 103(a) as being obvious over WO 93/14084 (WO '084). For at least the reasons that follow, withdrawal of the rejection is in order.

Independent Claim 121 defines a cosmetic or dermatological method for treating sensitive skin of an individual in need of such treatment, wherein said sensitive skin is in at least one cutaneous region of the individual's face, neck, hair and nails, and wherein said sensitive skin has such amount of substance P already released therein as to cause neurogenic manifestations of dyesthesia caused by the release of substance P therein, said sensitive skin being characterized by exhibiting at least one symptom selected from the group consisting of tingling, prickly, overheating, discomfort, tugging sensations, and desquamation; said method

comprising topically applying to said sensitive skin in said at least one cutaneous region of the face, neck, hair and nails and having such amount of substance P already released therein by exposure to and contact with at least one substance P-releasing active agent, an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P, and said at least one substance P antagonist being formulated into a topically applicable, cosmetically/dermatologically acceptable medium therefor. (Emphasis added.)

It is well-established that in order to demonstrate anticipation under 35 U.S.C. § 102(b), each feature of the claim at issue must be found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 218 U.S.P.Q. 789 (Fed. Cir. 1983). That is not the case here.

To establish a *prima facie* case of obviousness, the prior art reference must teach or suggest all of the claimed features. See In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). In addition, "all words in a claim must be considered in judging the patentability of that claim against the prior art." See In re Wilson, 424 F.2d 1382, 1385; 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970), and M.P.E.P. . 2143.03. Applicants submit that these requirements have also not been met.

Again, Applicants submit that WO '084 is directed to an allergic condition. WO '084 does not disclose or fairly suggest a cosmetic or dermatological method for treating sensitive skin of an individual in need of such treatment, wherein the sensitive skin is in at least one cutaneous region of the face, neck, hair and nails, has an amount of substance P already released therein and is characterized by at least one symptom selected from tingling, prickly, itching, pruritus, overheating,

discomfort, tugging sensations, and desquamation, the method comprising topically applying to said sensitive skin an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P, as claimed. (Emphasis added.) Instead, WO '084 is directed to antagonizing binding or interaction of substance P with NK_2 receptors. The NK_2 receptors are found in the smooth muscle not in the skin. (Again, see, for example, Abstract, Bianchi et al., JP Eur. Acad. Dermatol. Venereol., 1999 Jan. 12 (1); 6-10, which demonstrates that only NK_1 receptors are found in human skin.)

Furthermore, WO '084 relates to the use of piperdine derivatives, showing substance P antagonist activity, for analgesic or anti-inflammatory properties in the treatment of pathological disorders. The March 23, 2006, Declaration of Dr. De Lacharrière, M.D. (Director of Prospective Clinical Research in the Department of Advanced Research-Life Sciences) explains that the treatment of a pathological disorder showing inflammatory conditions is not sufficient to anticipate or render obvious the claimed methods directed to treating the non-pathological condition of sensitive skin. WO '084 provides no discussion concerning the symptoms and/or triggering factors of sensitive skin. Moreover, as explained in the Declaration, inflammation is not equivalent to sensitive skin.

To further support Applicants' position and to help the Examiner understand that the prior art methods of treating pathological disorders are distinguished from the claimed methods of treating the non-pathological disorder sensitive skin, Applicants provided copies of two studies (Appendix II and III to Dr. De Lacharrière's Declaration). The results obtained in the first study (see Appendix II) further demonstrate that the non-pathological condition of sensitive skin, unlike the

pathological condition being treated in WO '084, is a non-inflammatory condition. The study demonstrates that skin reactivity to lactic acid on the same group of individuals in the same study allowed Applicants to differentiate between people with sensitive skin and those with non-sensitive skin. (See, for example, Point 6 and the Conclusion of the study in Appendix II.) According to Dr. De Lacharrière, the study proves that people with sensitive skin do not have inflamed skin and that it is now possible to characterize a new group of individuals exhibiting specific signs distinct from those seen in individuals suffering from inflammation and allergy.

The second study (see Appendix III), provides results that indicate that a specific, limited population of European and American women were found to have sensitive skin. Dr. De Lacharrière explains that this rate is too high to be a pathological state, which is defined by the frequency and gravity of the disorder compared to a normal state. The study also proves again that there is no link between contact dermatitis and immunoallergologic diseases, or respiratory allergens and sensitive skin. (See Declaration at paragraph 10, page 4.)

WO '084 demonstrates no understanding of sensitive skin and proposes no specific treatment to address this problem. WO '084 discloses a method of treating a pathological condition; it does not disclose or fairly suggest treating the non-pathological, non-inflammatory condition of sensitive skin. From Dr. De Lacharrière's Declaration and the attached studies, it is clear that the individuals in WO '084 being treated for a pathological disorder are not individuals who are necessarily in need of the claimed methods for treating the non-pathological condition of sensitive skin, as required by Claim 121. The Official Action provides no scientific evidence or technical data to contradict this conclusion.

Furthermore, Applicants submit that sensations of discomfort are not the same as pain. Most manifestations of sensitive skin are subjective. This means that while the manifestations are not necessarily visible, they are felt by people with sensitive skin. No inflammation manifestation occurs in subjects with sensitive skin. In contrast, all of the disorders in the prior art (i.e., psoriasis, sun burn, pruritis) include inflammation. Prior to Applicants' discovery, no one knew that substance P was associated with sensitive skin. Thus, no person of ordinary skill in the art would have been motivated to use a substance P antagonist to treat sensitive skin. Furthermore, Applicants submit that Claim 121, which now specifies application to sensitive skin in at least one cutaneous region of the face, neck, hair or nails, is further distinguished from WO '084 because application is limited to areas of the body where sensitive skin disorders occur as opposed to other, more general cutaneous regions where the pathologies of the prior art are inclined to occur.

Because WO '084 does not expressly or inherently describe each feature of Claim 121, WO '084 cannot be relied on to support an anticipation rejection under 35 U.S.C. § 102(b).

In addition, because WO '084 does not teach or fairly suggest all of the claimed features and because the § 103(a) rejection over WO '084 does not consider all words in Claim 121 in "judging the patentability of that claim against the prior art," a *prima facie* case of obviousness over WO '084 cannot be established. For example, WO '084 provides no teaching, suggestion or consideration of "treating sensitive skin of an individual in need," "sensitive skin is in at least one cutaneous region of the individual's face, neck, hair and nails and wherein said sensitive skin has such amount of substance P already released therein," and "topically applying to

said sensitive skin . . . in said at least one cutaneous region of the face, neck, hair and nails an amount of at least one substance P antagonist."

Moreover, if it is the Official Action's position that WO '084 inherently anticipates or renders obvious the claimed method, Applicants respectfully submit that this position is also improper. Specifically, in order for prior art to anticipate a claimed invention on the ground that a feature is inherently disclosed in the reference, the inherency must be certain. The fact that a prior art reference may have the features of the claimed subject is not sufficient. Inherency must be a necessary result and not merely a possible result; the mere fact that a certain thing may result from a given set of circumstances is not enough. See In re Oelrich, 666 F.2d 578, 571, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981); Ex parte Keith and Turnquest, 154 U.S.P.Q. 320, 321 (Pat. Off. Bd. App. 1996). Accordingly, the Patent Office must provide evidence or scientific reasoning to establish the reasonableness of the Official Action's position that the claimed features are inherent characteristics of the prior art. See Ex parte Skinner, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Int. 1986).

The Official Action also fails to establish that the method of WO '084 would inherently render the claimed methods obvious because it has not shown that the methods of WO '084 inherently include all of the features of the claimed method. In order to establish a *prima facie* case, it is incumbent upon the Patent Office to establish the asserted inherency. See In re King, 231 U.S.P.Q. 136 (Fed. Cir. 1986). The Official Action must provide a basis in fact and/or technical reasoning to reasonably support the assertions that the allegedly inherent characteristic of the

WO '084 method necessary flows from the teachings of WO '084. See Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990).

Absent some additional teaching that establishes that the WO '084 method necessarily includes all the features of the claimed method, (e.g., "treating sensitive skin of an individual in need of such treatment," "sensitive skin is in at least one cutaneous region of the individual's face, neck, hair and nails, and wherein said sensitive skin has such amount of substance P already released therein," "topically applying to said sensitive skin in said at least one cutaneous region of the face, neck, hair and nails . . . an amount of at least one substance P antagonist," etc.), the Official Action fails to establish the asserted inherent characteristics of the WO '084 method. Moreover, any such additional teaching relied on for the purpose of establishing inherency of the features and/or operation of the WO '084 method, "must make clear that the missing descriptive matter is necessarily present in the thing (the WO '084 method) described in the reference and that it would be so recognized by persons of ordinary skill." See Continental Can Co. v. Monsanto Co., 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). The Official Action does not identify any such additional teaching.

In the present case, the Official Action does not provide any evidence or scientific reasoning to support a position of inherent anticipation or obviousness. Because independent Claim 121 is directed to a method for treating sensitive skin of an individual in need of such treatment, the claimed method cannot be inherently anticipated or rendered obvious by WO '084, which is directed to treating a population of individuals suffering from a different pathological, inflammatory condition. That is, it cannot be shown that those being treated for the pathological,

inflammatory condition disclosed in WO '084 are necessarily individual subjects in need of such treatment having sensitive skin wherein such an amount of substance P is already released therein as to cause neurogenic manifestations of dyesthesia caused by the release of substance P therein, and characterized by at least one of the symptoms selected from the group defined in Claim 121. In the May 2006 Declaration, Dr. De Lacharrière, a respected expert with more than ten years of research experience in the field of dermatophysiology, explains that it is his professional opinion (supported by the studies in Appendices II and III) that people with sensitive skin do not have inflamed skin and that the population of individuals who have sensitive skin is a specific, limited population that only includes individuals who exhibit signs distinct from those seen in inflammation and allergy.

Additionally, it has been decided that in order to establish anticipation or obviousness by inherency, it must be shown that one of ordinary skill in the art would reasonably expect the claimed invention from the disclosure of the cited reference. If the disclosure of the reference coupled with the knowledge of the ordinary skilled worker does not lead one of ordinary skill to reasonably expect the claimed invention, there can be no anticipation or obviousness. Specifically, it is not immaterial that Applicants have discovered that a substance P and antagonist possesses utility as a agent to reduce or eliminate an amount of already released substance P in a cosmetic or dermatological method for treating sensitive skin. This utility was not previously known, nor would it have been reasonably expected by the ordinary skilled worker reading WO '084. The use of a substance P antagonist as an analgesic or anti-inflammatory is very different from reducing or eliminating an amount of already-released substance P for treating sensitive skin of an individual in

need. Applicants believe that it is highly surprising that they have found that a substance P antagonist can be used to treat sensitive skin. Moreover, even if a substance P antagonist were administered in the present claims in a manner similar to the manner of administration in WO '084, Applicants wish to point out that the methods of WO '084 will be practiced on individuals wanting to reduce or eliminate pain or inflammation. In contrast, Applicants' method is to be practiced on individuals who are in need of sensitive skin treatment using a method that includes *inter alia* topical application of an effective amount of a substance P antagonists to sensitive skin in at least one cutaneous region of the individual's face, neck, hair or nails.

Also worth pointing out is the C.C.P.A. decision in In re Marshall, 578 F.2d 301; 198 U.S.P.Q. 344 (C.C.P.A. 1978) wherein the court reversed a Board of Appeals' decision sustaining a 35 U.S.C. § 102 rejection of Claims 1-4.

In In re Marshall, appellants' invention, as claimed in claims 1-4, was a weight control process in which an effective amount of an anesthetic oxethazaine, was administered to inhibit release of the pancreatic secretory hormones so as to control weight. The rejection of these claims was reversed because the primary reference, the PDR (Physician's Desk Reference), did not disclose every material element of the claimed subject matter. The court said that the PDR taught the use of oxethazaine to inhibit release of the acid-stimulating hormone, gastrin, to treat certain digestive disorders; but that the PDR did not remotely suggest taking oxethazaine to lose weight. The rejection of claims 1-4 was therefore reversed. Whether or not the dosages of the two uses overlapped, played no role in the decision in the § 102 rejection; the key holding was that the reference did not

disclose using the drug to lose weight. The court also stated: "If anyone ever lost weight following the PDR's teaching, it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation." (Emphasis added.) Similarly, in the present case, WO '084 does not anticipate Applicants' claims because WO '084 does not disclose or even remotely suggest topically applying a substance P antagonist to sensitive skin to reduce or eliminate an amount of already released substance P in a method for treating sensitive skin of an individual in need of such treatment.

Because the claimed use of a substance P antagonist is neither disclosed nor suggested anywhere in WO '084, Applicants submit that it is improper to assert that the claimed method is inherently anticipated or rendered obvious by WO '084. That is, Applicants submit from the disclosure of WO '084 there is not even a reasonable likelihood that the trained observer could have discovered or recognized the claimed method without specific guidance from the instant application. Inherent anticipation by WO '084 cannot be properly established in the present case under the principles generally followed in construing 35 U.S.C. § 102 because the subject matter said to be anticipated is not disclosed in the reference in a manner sufficient to place it in the possession of the public. See Akzo v Intn'l Trade Comm'n, 808 F.2d 1471, 1479, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986); In re Samour 571 F.2d 559, 562, 197 U.S.P.Q. 1, 3 (C.C.P.A. 1978) and cases cited therein.

Also notable is the Federal Circuit's very recent decision in Perricone v. Medicis Pharm. Corp., Slip Op. No. 05-1022, -1023 (Fed. Cir. December 20, 2005). In Perricone, the Court was reviewing a decision by the U.S. District Court for the District of Connecticut, which held that certain claims of U.S. Patent No. 5,409,693

(the '693 patent) were invalid as inherently anticipated. The claims of the '693 patent are directed to methods of treating or preventing sunburn by topically applying to skin sunburn a fatty acid ester of ascorbic acid. The District Court held that U.S. Patent No. 4,981,845 (the '845 patent) anticipates various claims of the '693 patent.

The '845 patent discloses a cosmetic composition for topical application, which includes various ingredients including skin benefit ingredients (including ascorbyl palmitate) emollients, emulsifiers, and thickeners. The '845 patent only briefly identifies the compositions and states that they are "suitable for topical application to skin or hair." ('845 patent, col. 1, lines 6-8) The District Court held that topical application of the '845 patent's compositions would necessarily yield the results of the '693 patent's claimed methods. Specifically, the District Court based its anticipation analysis on inherency stating that the method of the '845 patent "will inherently function in [the claimed beneficial manner] when topically applied to the skin." See Perricone, 267 F. Supp. 2d at 248.

The Federal Circuit in reversing the District Court stated that the issue is not whether the lotion of the '845 patent if applied to skin burn would inherently treat that damage, but whether the '845 patent discloses the application of its composition to skin sunburn, which the Court determined it does not. In support of its decision, the Federal Circuit relied on Catalina Marketing International, Inc. v. Cool Savings.com, Inc., 289 F.3d 801, 809 (Fed. Cir. 2002), which held that a patent on an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. The Federal Circuit also noted that 35 U.S.C. § 101 specifically indicates that new uses of old products or processes are indeed patentable subject matter. The Court also cited In re King, 801 F.2d 1324, 1326

(Fed. Cir. 1986) which held that the principles of inherency do not prohibit a process patent for a new use of an old structure.

Ultimately, the Federal Circuit held that the District Court's inherent anticipation analysis was flawed because the '845 patent's use of a lotion (i.e., topical application) does not suggest application of the '845 patent's lotion to skin sunburn. The Federal Circuit explained that the District Court's inherency analysis went astray because "it assumes what Pereira [the '845 patent] neither disclosed nor rendered inherent. Because Pereira does not disclose topical application to skin sunburn, this court reverses the District Court's holding . . ." (Emphasis added.)

Applicants submit that the rejections in the outstanding Official Action are analogous to the District Court's holding reversed by the Federal Circuit in Perricone. Here, the process of Claim 121 is specifically directed to the topical application of a substance P antagonist to sensitive skin in at least one cutaneous region of the face, neck, hair or nails. None of the cited prior art references (including WO '084) disclose or fairly suggest this feature of Claim 121. Thus, as in Perricone, it is improper to conclude that the methods of the prior art directed to the treatment of other, different conditions inherently anticipate the claimed methods because this conclusion would assume what the prior art neither discloses nor renders inherent (i.e., topical application of a substance P antagonist to sensitive skin in at least one cutaneous region of the face, neck, hair or nails.)

For at least these reasons, Applicants submit that Claim 121 is patentable over WO '084. The remaining claims (Claims 26, 28-50, 53 and 54) depend, either directly or indirectly, from Claim 121 and are therefore also patentable over WO '084

for at least the reasons that Claim 121 is patentable. Reconsideration and withdrawal of the §§ 102(b)/103(a) rejection over WO '084 is respectfully requested.

Claims 26, 28-50, 53-54, 116 and 121 stand rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (Contact Dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252 and WO 93/14084, individually or in combination. For at least the reasons that follow, withdrawal of the rejection is in order.

As explained above, to establish a *prima facie* case of obviousness, the prior art references (or references when combined) must teach or suggest all of the claim features and the rejection must demonstrate proper consideration of all words in the rejected claims in judging the patentability of the claims in the prior art. See In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974); In re Wilson, 424 F.2d at 1385, 165 U.S.P.Q. at 496; and M.P.E.P § 2143.03. The present § 103(a) rejection does not meet these requirements.

Again, independent Claim 121 is specifically directed to a method for treating sensitive skin of an individual in need of such treatment wherein the sensitive skin is in at least one cutaneous region of the individual's face, neck, hair or nails and wherein said sensitive skin has such an amount of substance P already released therein as to cause neurogenic manifestations of dyesthesia and is characterized by exhibiting at least one symptom selected from a specified group of symptoms. In addition, the method specifically includes in the combination of claimed features a step of topically applying a substance P antagonist to sensitive skin in said at least one cutaneous region of the face, neck, hair and nails. The various disorders being treated by the methods disclosed in the cited prior art references cannot be relied

upon to support a rejection of obviousness because they relate to the treatment of pathological disorders while the claimed method is directed to the treatment of the non-pathological condition sensitive skin. Nowhere do the cited references, alone or in combination, disclose or fairly suggest the combination of features defined in Claim 121, including, for example, "treating sensitive skin of an individual in need," "sensitive skin is in at least one cutaneous region of the individuals face, neck, hair and nails wherein said sensitive skin has such amount of substance P already released therein," and "topically applying to said sensitive skin in said at least one cutaneous region of the face, neck, hair and nails. . . an amount of at least one substance P antagonist."

As indicated in the Declaration of Dr. De Lacharrière, both of the Wallengren articles relate to an allergic condition such as contact dermatitis or irritant delayed reaction. WO '252 relates to a drug based on a substance P antagonist for the treatment of inflammation or diseases showing inflammatory conditions. WO '084 relates to piperdine derivatives showing substance P antagonist activity wherein the derivates may be used for analgesic or anti-inflammatory applications. Applicants have studied these references and concluded that they are each directed to the treatment of pathological disorders showing inflammatory conditions. In stark contrast, the claimed methods are directed to the treatment of the non-pathological condition, sensitive skin. In the Declaration, Dr. De Lacharrière explains, however, that the specific state of sensitive skin is not equivalent to inflammation and is a condition quite different from the allergic, pathological disorders being treated in the cited references. None of the cited references, alone or in combination, overcome these deficiencies. The cited references merely disclose methods of treating other,

different diseases, that commonly occur in other cutaneous regions, which may exhibit one isolated symptom of sensitive skin.

In the first study (Appendix II) attached to Applicants' Declaration, Applicants conducted a cerebral activity analysis and found that brain activation was induced by discomfort sensory stimuli in people with sensitive skin. Again, Applicants submit that the study demonstrates that the non-pathological condition of sensitive skin, unlike the pathological conditions being treated in the cited references, is a non-inflammatory condition. The study proves that people with sensitive skin do not have inflamed skin. In addition, Dr. De Lacharrière has explained and the two studies (Appendices II and III) attached to his Declaration prove that the population of individuals who have sensitive skin is a specific, limited population.

Accordingly, Applicants submit that a *prima facie* case of obviousness over the above cited combination of references cannot be established because the asserted combination of references does not teach or suggest all of the claimed features and does not provide proper consideration of all words in Claim 121 in judging the patentability of the claim against the prior art. Specifically, the cited references, alone or in combination, provide no teaching, suggestion or consideration of "treating sensitive skin of an individual in need of such treatment," "sensitive skin is in at least one cutaneous region of the individual's face, neck, hair and nails and wherein said sensitive skin has such amount of substance P already released therein," "sensitive skin being characterized by exhibiting at least one symptom selected from the group consisting of tingling, prickly, overheating, discomfort, tugging sensations, and desquamation," "topically applying to said sensitive skin in said at least one cutaneous region of the face, neck, hair and nails

having such amount of substance P already released therein," and "an amount of at least one substance P antagonist effective to reduce or eliminate such amount of said already released substance P," in Claim 121.

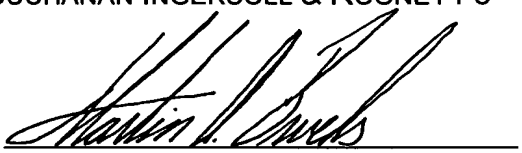
Furthermore, it is improper to assert that the above-cited combination of references inherently renders obvious the claimed methods because the Official Action fails to establish that the combined references "inherently" include all of the features of Claim 121. To establish a *prima facie* case of inherent obviousness, it is incumbent on the Patent Office to establish the asserted inherency. See In re King, 231 U.S.P.Q. 136 (Fed. Cir. 1986). There must be a basis and fact and/or technical reasoning to reasonably support the assertion that the allegedly inherent features of the process necessarily flow from the teachings of the references cited. See Ex parte Levy, 17 U.S.P.Q.2d at 1464. Without this additional teaching to establish that the methods of the cited references necessarily include all of the features of Claim 121, the Official Action fails to establish the asserted inherent obviousness. Moreover, any such additional teaching relied on for the purpose of establishing inherency of the claimed method, "must make clear that the missing descriptive matter is necessarily present in the thing (the methods) described in the references and that it would be so recognized by persons or ordinary skill." See Continental Can Co. v. Monsanto Co., 20 U.S.P.Q.2d at 1749. The Official Action presents no such additional teaching.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the §103(a) rejection over the above-asserted combination of references.

From the foregoing, Applicants earnestly solicit further and favorable action in the form of a notice of allowance. If there are any questions concerning this paper or the application in general, Applicants invite the Examiner to telephone the undersigned at the Examiner's earliest convenience.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: December 18, 2006 By: 

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